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Patent  
Case No: 48317US014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Group Art Unit: 3761

Serial No.: 08/240,877

Filed: May 11, 1994

Examiner: A. Lewis

For: UNIDIRECTIONAL FLUID VALVE

DECLARATION OF JOHN L. BOWERS

I, John L. Bowers, state as follows:

2. I have been working in the respiratory field for about the past 15 years and am very familiar with the art pertaining to personal respiratory protection devices, including filtering face masks that are worn over the nose and mouth of a person and that use an exhalation valve to purge warm, moist, exhaled air from the mask interior.

3. I hold two U.S. patents in the respiratory field, including U.S. Patent 5,687,767 to Bowers, originally assigned to Racal Health & Safety Limited, England. This patent describes a unidirectional flapper-style fluid valve that is useful as an exhalation valve on a filtering face mask.

4. I am familiar with the subject matter of the above-captioned application.

5. I used to be an employee at Racal Health & Safety Limited prior to the acquisition of its assets by 3M. I worked at Racal for 9 years and had the title of operations and technical manager. In that position, I was responsible for health and safety product development, particularly for respiratory masks.

6. I presently hold the position of site manager in the Occupational Health & Environmental Safety Products Division (OH&ESD) at the 3M Company, 12-16 Bristol Road, Greenford Middlesex, England. In this position I am responsible for the day to day operation of the manufacturing and distribution centers for powered and supplied air respirators.

7. While working at Racal, I was assigned the responsibility to develop a new exhalation valve for its respiratory masks. Racal had a number of customer requests for a mask

EXHIBIT B

that had an exhalation valve to purge warm, moist air from the mask interior. In considering candidates for exhalation valves on our respiratory products, I initially looked at conventional button-style valves. These valves, however, were not selected for widespread commercialization of Racal face masks because the cracking pressure required to open the button-style valve was found to be relatively high. I found that the central pivoting point created an undesirably higher opening force.

8. As part of the process for designing a new valve, I examined the exhalation valve that was recently commercialized by 3M. This valve is described in U.S. Patent 5,325,892 to Japuntich et al. I not only examined an actual commercial embodiment of the 3M valve, but I also carefully reviewed the disclosure of the '892 3M patent.

9. My evaluation of the 3M valve showed a product that had better performance than the conventional button-style valves. This evaluation led me in pursuit of developing a flapper-style valve similar to the 3M valve. The valve that was ultimately designed by me for Racal was the flapper-style unidirectional fluid valve that is shown in U.S. Patent 5,687,767 to Bowers, and a sample of which is attached to this Declaration as Exhibit G. I sought to design a valve that would avoid infringement of the issued 3M '892 patent and would be patentable over its disclosure. The filtering face mask that was developed, which employed the new Racal valve that I developed, did possess some features similar to the 3M valve and borrowed technology learned from the 3M valve. In particular, I designed the exhalation valve for Racal so that the flexible flap of the Racal valve was secured non-centrally relative to the orifice and had a free portion that was pressed against the seal surface when a wearer was neither inhaling nor exhaling, and the flap had a curvature in the free portion when viewed from the side elevation in a closed position (although the Racal valve that I designed was also made to have a transverse curvature). The flap was also designed to have stationary and free portions with a circumferential or peripheral edge that had stationary and free segments, respectively. The flap was secured to the valve seat at the flap-retaining surface closer to the stationary segment of the peripheral edge than to the free segment. Other than the transverse curvature, the features described in the three previous sentences were present in the 3M valve and were discovered from my examination of the 3M product and the published '892 patent. The Racal valve thus was able

to remain closed under neutral conditions under any orientation, like the 3M valve, to prevent the influx of contaminants and was also able to open under a relatively small exhalation force.

10. I have also read U.K. Patent Application GB 2072516 to Simpson et al. (Simpson) and U.S. Patent 3,191,618 to McKim, and I do not believe that the combination of Simpson and McKim would have led a person of ordinary skill in the art to the present invention. In my view, the McKim patent is not pertinent to the subject matter sought to be patented in the above-captioned U.S. Patent Application Serial No. 08/240,877 and is not pertinent to the subject matter taught in Simpson.

11. My review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.

12. The field of the above-captioned '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow warm, moist, exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves generally operate at normal room temperatures and pressures.

13. The field of endeavor for filtering face mask is very different from the field of endeavor of a reed valve that is used in a two-cycle engine. Exhalation valves for respirators operate under very different conditions from valves that are used in two-cycle engines and require notably different design parameters. The valve that is described in McKim has very rapid opening and closing requirements (thousands of openings and closings per minute) and operates under temperatures and pressures that differ substantially from the requirements of exhalation valves, which open and close under the much slower pace of a wearer's breathing and under temperatures and pressures that tend to vary only from the ambient to that exhibited by the wearer's exhaled air. Thus, persons of ordinary skill in the field of designing filtering face

masks, to the best of my knowledge and experience, do not find valves for two-cycle engines to be in their field of endeavor and therefore do not consult documents that describe valves for these engines when developing new respiratory products.

14. In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

15. My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior

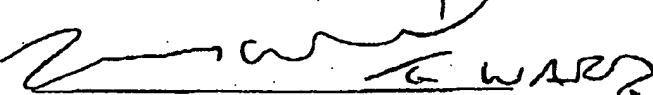
when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

16. The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated this Tenth day of December, 2001.

  
John L. Bowers

  
Witness

  
Witness

STUART MILLER